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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,835	11/20/2001	Herve Perron	110631	1488

7590 11/29/2004

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,835	PERRON ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) *14-17,23-31 and 41-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,18-22 and 32-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group 1, Claims 1-13, 18-22 and 32-40, with traverse, in the paper filed 9/03/04 is acknowledged. Applicant argues that "the search and examination of the all of claims 1-13, 18-22, 32-52 and 73 could be made without serious burden". Applicant is advised that because the application was filed as a national stage PCT application serious burden is not a consideration in requiring restriction. The application has been restricted under the rules for restricting national stage PCT applications as set forth in Chapter 1800 of the M.P.E.P., not the rules as set forth in Chapter 800 of the M.P.E.P.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 14-17, 23-31, and 41-74 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 1-13, 18-22 and 32-40 are being acted upon.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-13, 18-22 and 32-40 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Note that all claims ultimately depend from independent Claims 1 and 32. Claims 1 and 32 recite a method for detecting SAg activity in a biological sample. The omitted steps comprise some sort of active method steps that would result in said detection. While some of the dependent claims include some active steps, none of the claims comprise a proper resolution. For example, Claim 7 recites a method for detecting SAg activity comprising culturing cells, contacting the supernatant from said culture with a second culture of cells, and no other actual steps. Proper additional steps might include assaying/measuring the effect of the supernatant on the expansion or loss of the second culture of cells wherein expansion indicates one outcome (i.e., detection of SAg activity) and loss indicates another outcome.

5. Claims 1-13, 18-22 and 32-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically:

A) The term "superantigen" is vague and indefinite given the definition at page 4 of the specification that the term "superantigen" encompasses "molecules having properties close to certain effects which superantigens are known to have", said "properties" and "effects" (and "properties" and "effects" "close" to those "properties" and "effects") being undisclosed.

B) The phrase "a method ... *characterized* in that" is vague and indefinite. It is unclear what "characterized" means in the instant context. Accordingly, the metes and bounds of the claimed invention cannot be determined.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-13, 18-22 and 32-40 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Elements critical or essential to the practice of the invention, but not included in the claims are not enabled by the disclosure. The instant claims recite a method for detecting SAg activity in a biological sample. The steps set forth in the claims, however, do not result in said detection. While Claims 1 and 32 include no method steps, even claims, e.g., Claim 7, which do include actual method steps, result in the detection of expansion, co-expansion, loss, and/or co-decrease of cultured cells, and not SAg activity. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

8. Claims 37-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar* , 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in

possession of the invention, and that the invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of "fragments" of SEQ ID NOS:1 and 2, capable of functioning in the claimed methods. Given the disclosure of none of the claimed fragments, and the unlimited number of fragments encompassed for use in the method of claims, one of skill in the art would conclude that the specification fails to disclose a representative number of species to describe the claimed genus. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-13, 18-22 and 32-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/05527 in view of U.S. Patent No. 5,336,598, Komurian-Pradel et al. (1998), and Herrmann et al (1994).

WO 99/05527 teaches a method of detecting retroviral SAg activity in a biological sample taken from an autoimmune disease patient, said method comprising testing levels of particular Vβ usage in said patient (see particularly page 11, IV: SAg activity specifically associated with the autoimmune disease and page 17, second full paragraph)

The reference teaching differs from the claimed invention only in that it does not teach a method wherein the SAg is derived from patient cell culture supernatant and the detection of Vβ16 and an additional Vβ in an MS patient and a method employing the polypeptide of SEQ ID NO:2 .

The '598 patent teaches a method wherein a difference of Vβ usage levels between a test patient and normal Vβ usage is considered to be indicative of a disease (see particularly column 3, lines 22-28). The reference further teaches a method wherein the SAg induces the expansion (stimulation) of T cells (blood mononucleated cells bearing particular Vβs as well as methods comprising the measurement of mRNA levels (see particularly columns 3-4, Example 2).

Komurian-Pradel et al. teaches that the MSRV-1 retrovirus (which would comprise SEQ ID NOS:1 and 2) is associated with and found in MS patients (see entire abstract).

Herrmann et al. teaches the expansion of Vβ16-expressing (and other, e.g., Vβ8) T cells (blood mononucleated cells) in response to SAg (see particularly Table 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method of detecting retroviral SAg activity in a biological sample taken from an autoimmune disease patient, said method comprising testing levels of particular Vβ usage in said patient, as taught by WO 99/05527, employing the methods of the '598 patent, wherein the autoimmune patient is an MS patient and the method employs the MSRV-1 retrovirus, as taught by Komurian-Pradel et al. in an assay for Vβ16. One of ordinary skill in the art at the time the invention was made would have been motivated to combine the methods because the '598 patent teaches that particular Vβ usage is associated with disease, in particular retroviral associated autoimmune disease, as taught by WO 99/05527. The additional teachings of Komurian-Pradel et al. that the MSRV-1 retrovirus is associated with MS and Herrmann et al. that expansion of Vβ16-expressing (and other, e.g., Vβ8) T cells is associated with SAg, render the method of the instant claims, i.e., detecting SAg activity in a sample by measuring SAg activity, obvious.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

Please Note: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Inquiries of a general nature may also be directed to the Technology Center 1600 Receptionist at (571) 272-1600.

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11/24/04

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